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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/665,728	09/20/2000	Lawrence W. Stanton	SCIOS.013A	8743

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EXAMINER
O HARA, EILEEN B

ART UNIT	PAPER NUMBER
1646	12

DATE MAILED: 04/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/665,728	Applicant(s) STANTON ET AL.	
	Examin r Eileen B. O'Hara	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 February 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 September 2000* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5,7,8* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Claims 1-8 are pending in the instant application. Claim 1 has been amended and claims 9-29 have been canceled as requested by Applicant in Paper Number 11, filed Feb. 4, 2002.

Election/Restrictions

2. Applicant's election of Group I in Paper No. 11, claims 1-8, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Formal Matters

3. Applicants request for a corrected filing receipt filed Jan. 29, 2001 has been entered.

Drawings

4. The drawings are objected to because the sequence in Fig 2 is too close to the top of the page, and subsequently the holes punched in the top have obliterated parts of the top lines. See MPEP 37 CFR 1.84 (g) Margins:

The sheets must not contain frames around the sight (i.e., the usable surface), but should have scan target points (i.e., cross-hairs) printed on two catercorner margin corners. Each sheet must include a top margin of at least 2.5 cm. (1 inch), a left side margin of at least 2.5 cm. (1 inch), a right side margin of at least 1.5 cm. (5/8 inch), and a bottom margin of at least 1.0 cm. (3/8 inch), thereby leaving a sight no greater than 17.0 cm. by 26.2 cm. on 21.0 cm. by 29.7 cm. (DIN size A4) drawing sheets, and a sight no greater than 17.6 cm. by 24.4 cm. (6 15/16 by 9 5/8 inches) on 21.6 cm. by 27.9 cm. (8 1/2 by 11 inch) drawing sheets.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 101 and § 112

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 1-8 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility. Claims 1-8 are directed to nucleic acids encoding the protein of SEQ ID NO: 1, identified as clone P00210_D09 (nucleic acid of SEQ ID NO: 2). The instant specification discloses that the polypeptide of P00210_D09 is a 275 amino acid protein, and that it is a secreted protein based on the presence of a putative signal sequence (amino acids 1-21), and that the protein has two putative membrane spanning segments from amino acids 35-55 and 123-143. The specification teaches that P00210_D09 encodes a rare message, and that the sequence of P00210_D09 was compared with sequences in the public GenBank, EMBL, DDBJ and GENESEQ databases, and the search revealed no significant homology with sequences present in the searched databases.

Clone P00210_D09 was identified using differential gene expression assays, in which the left ventricles of male rats were surgically manipulated to produce a myocardial infarction (MI), tissue was collected at 2, 4, 8, 12 and 16 weeks post-surgery, and used to produce mRNA for microarray analysis. Septum tissue was also obtained from diseased rat hearts as in the same MI

model, and mRNA was also produced and analysed by microarray analysis. From the microarray results, the expression level of the gene corresponding to the clone referred to a P00210_D09 was 2.1-fold higher at the 2 week time point in the rat left ventricle and 1.8-fold higher at the 2 week time point in the septum, which suggests the possible involvement of this gene in the development and/or progress of MI (Fig. 6). The specification teaches that this gene can be screened to obtain more information about the biological function of gene and encoded protein, and that this further information can lead to the designation of this gene or similarly differentially expressed genes or their gene products as potential therapeutic or diagnostic molecules or targets for identifying such molecules (pages 24-25). Though this differential expression after myocardial infarction is scientifically interesting and potentially useful, the nucleic acids and encoded protein do not have any specific and substantial utility, or a well established utility, as determined according to the current Utility Examination Guidelines, Federal Register, Vol. 66, No. 4, pages 1092-1099, Friday, January 5, 2001.

Use of clone P00210_D09 to discover its biological function and possible role in disease states is not a specific and substantial utility, and is only further research to discover what the activities and biological significance of the protein and encoding nucleic acid are. At the present time, clone P00210_D09 cannot be used diagnostically or therapeutically, because there is no biological activity known for the protein, and there is no information provided that suggests that P00210_D09 could be used as a diagnostic before the onset of disease.

The instant application also asserts other used of the polynucleotides and endcoded protein, such as use to design specific oligonucleotide probes and primers, screening libraries for genomic DNA and other full-length sequences, rapid analysis of cell, tissue or peripheral blood

samples, vector constructs, antibody production and production of transgenic animals. However, these are general methods that would apply to virtually any protein, and are not specific to this particular protein or encoding polynucleotide.

In Brenner v. Manson, 148 U.S.P.Q. 689 (Sus. Ct,.1966), a process of producing a novel compound that was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be useful because the compound produced thereby was potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. § 101, which requires that an invention must have either an immediately obvious or fully disclosed "real world" utility. The instant claims are drawn to a polynucleotide encoding a protein which has undetermined function or biological significance, and the use of a gene to discover its potential significance or biological properties does not constitute a specific, substantial utility. All of the biological activities of a protein need not be known to obtain a patent, but there must be some specific and substantial activity or function known. It is possible that after further characterization, this polynucleotide or protein might be found to have a patentable utility, such as differential expression in a subject prone to myocardial infarction. This further characterization, however, is part of the act of invention, and until it has been undertaken the Applicants' claimed invention is incomplete. Because there is no specific and substantial utility asserted, credibility cannot be assessed.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6.1 Claims 1-8 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. Even if the specification were enabling of how to use the P00210_D09 (or nucleic acid), enablement would not be found commensurate in scope with the claims. If one of skill in the art does not know how to use the nucleic acids or proteins the skilled artisan would clearly not know how to use polynucleotides that encode a polypeptide that is at least 80%% identical to the polypeptide of SEQ ID NO: 1, or polynucleotide hybridizing under stringent conditions to the polynucleotide of SEQ ID NO: 2.

6.2 Claims 1 and 5-8 are also rejected because claim 1 encompasses a polynucleotide encoding a polypeptide having at least about 80% sequence identity with amino acids 22-122 or 56-122 of SEQ ID NO: 1, and the specification on page 12 recites amino acid sequence variants having 75%, 85%, 90% and 95% sequence identity with the polypeptide of SEQ ID NO:1, and therefore 80% is new matter.

6.3 Claims 1 and 5-8 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification describes a polypeptide sequence consisting of SEQ ID NO:1. However, the claims as written include polynucleotides encoding polypeptides comprising variants and encompass polypeptides that vary substantially in length

and also in amino acid composition. The instant disclosure of a single polypeptide, that of SEQ ID NO: 1 with no known specific activities, does not adequately support the scope of the claimed genus, which encompasses a substantial variety of subgenera. A genus claim may be supported by a representative number of species as set forth in *Regents of the University of California v Eli Lilly & Co,* 119F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997), which states:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention". Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1980) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.") Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d 1565, 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id at 1170, 25 USPQ2d at 1606."

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus, or of a recitation of structural features common to the genus, which features constitute a substantial portion of the genus. The instant specification discloses, however, a single isolated

polypeptide sequence SEQ ID NO: 1, and no activity is set forth for the additional sequences. There is no correlation or nexus provided between possession of any structural features of SEQ ID NO: 1 and any activity such that it is clearly conveyed that possession of any polypeptide having this structural region in common would possess these functional features. The instantly claimed genus is not so limited and the prior art does not provide compensatory structural or correlative teachings to enable one of skill to identify the polynucleotides encompassed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are indefinite because claim 1 encompasses a nucleic acid molecule which hybridizes under "**stringent conditions**". Though the specification on pages 12-13 describes various hybridization and wash conditions, they are exemplary. The term **stringent conditions** is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired.

Conclusion

8.1 No claim is allowed.

8.2 The art considered pertinent to the present application is Marra et al., Database EST, Accession No. AI449932 (Mus musculus cDNA clone IMAGE:603821), March 9, 1999 (cited by Applicants) which discloses a polynucleotide which is 92.8% identical to nucleotides 19-367

of SEQ ID NO: 2 of the present application (see attached alignment). This reference but is cited as the nucleic acid sequence having the closest homology.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers Before Final filed by RightFax should be directed to (703) 872-9306.

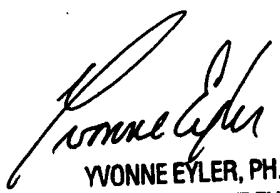
Official papers After Final filed by RightFax should be directed to (703) 872-9307.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D.

Patent Examiner



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